#### **REMARKS**

This paper is prepared in response to the outstanding Office action (Paper No. 20070816) mailed 22 August 2007.

#### Status of the Claims

Claims 1 through 14 are pending in the application, of which claim 2 was previously canceled.

# **Listing of the Claims**

Pursuant to 37 CFR §121(c), the claim listing, including the text of the claims, will serve to replace all prior versions of the claims, in the application.

## Amendment of the Abstract

In response to the objection to the Abstract, the Abstract of this application is newly added in a single paragraph on a separate sheet.

### **Amendment of the Claims**

Claim 1 has been amended to add the feature of "the magnesium titanate oxide film comprising an upper porous layer and a lower barrier layer" and to make a cosmetic change.

Claim 3 has been amended to add the description of "in an atomic ratio based on the total atoms of the magnesium titanate oxide film", which is supported by paragraph [0015]

Claim 4 has been canceled without disclaiming its subject matter.

### **Specification**

The Abstract of the disclosure was objected to because it was filed as the first page of International Publication No. WO 2005/084577, rather than as a single paragraph on a separate sheet.

Accordingly, the Abstract is now set forth in a separate single paper and being concurrently submitted with this Amendment. Withdrawal of the objection to the specification is therefore respectfully requested.

## Claim Rejections - 35 U.S.C. § 112

Claims 3 and 16 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 has been amended to add the description of "based on the total weight of the magnesium titanate oxide film"

Withdrawal of the objection is respectfully requested.

### Claim Rejections - U.S.C. § 103

Claims 1, 5, 6, 19 and 20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Vizethum *et al.* (DE 4407993) in view of Kamiya *et al.* (JP 2003-268481), and further in view of Chang *et al.* (KR 9208348).

Claims 1, 4-8, 15, 17 and 19-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Vizethum *et al.* (DE 4407993) in view of Kamiya *et al.* (JP 2003-268481) and further in view of Chang *et al.* (KR 9208348), and still further in view of Hall *et al.* (WO 00/72777 A1) and Kruger (DE 2135004).

Claim 1 has been amended to recite the feature of "the magnesium titanate oxide film comprising an upper porous layer and a lower barrier layer". Accordingly, claim 4 has been

canceled.

The examiner argued that Vizethum et al. teach an implant comprising a titanium or titanium alloy implant body (2, 4) having a suitable oxide layer (30, 31), Kamiya et al. teach a composite suitable for use in implantation formed by sintering a mixture of magnesium oxide and titanium. The examiner also argued that the above arguments establish a rationale tending to show the claimed product is the same as what is taught by the prior art.

The examiner's reasoning is not proper for the following reasons.

First, Kamila et al. does not teach the magnesium titanate oxide.

The examiner relied on Chang et al. (KR 9208348) to show that sintering a mixture of magnesium oxide and titanium is expected to produce magnesium titanate oxide.

It should be noted that the reaction condition and the reactants (e.g., <u>Ti-oxide</u> in Chang et al. and <u>Ti matrix</u> in Kamila) of Kamila et al. and Chang et al are substantially different from each other. In addition, Kamila et al. expressly stated that their invention is directed to a titanium radical <u>composite</u> material having strength enhanced by dispersing magnesium oxide particles in a matrix comprising a titanium material to form a composite, whereas Chang et al. '348 is directed to MgTiO<sub>3</sub>. Thus, the <u>composite</u> of Kamila et al. is different from <u>MgTiO<sub>3</sub></u> of Chang et al. which is not believed to be a composite which is defined as "[c]omposite materials (or composites for short) are engineered materials made from two or more constituent materials with significantly different physical or chemical properties and <u>which remain separate and distinct on a macroscopic level within the finished structure"</u> (quoted from wikipedia.com (<a href="http://en.wikipedia.org/wiki/Composite\_material#Examples\_of\_composite\_materials>.)"

The examiner unreasonably regarded the titanium composite in which the magnesium oxide

is distributed as magnesium titanate oxide.

Therefore, the examiner's reasoning is not proper.

Withdrawal of the rejection is respectfully requested.

**Second**, the magnesium titanate oxide film is different from MgTiO<sub>3</sub> produced by sintering.

The applicant expressly explained in the specification that the magnesium titanate oxide film produced by anodic oxidation of the surface of the implant body in a single or mixed solution containing magnesium. For example, at paragraph [0022], it is described that "the osseoinductive magnesium titanate oxide film implant in accordance with the present invention comprise an implant body 1 made up of titanium or a titanium alloy and magnesium titanate oxide films 2 and 3, the magnesium titanate oxide film being further divided into the surface porous oxide layer 3 and a barrier oxide layer 2 formed between the surface and implant body."

This structure cannot be made by Vizethum et al., Kamiya et al., or in combination thereof.

Therefore, the examiner did not show that the claimed product is the same as what is taught by the prior art.

Third, there is no reasonable expectation of success in combining Vizethum et al. and Kamiya et al.

The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

It is known that, in the anodization, the current releases hydrogen at the cathode (the negative electrode) and oxygen at the surface of the anode (e.g., Al, Ti), creating a build-up of oxide (e.g., aluminum oxide or titanium oxide).

That is, the anodic oxidation results in anion incorporation. Therefore, the phenomenon of cations Mg incorporation into titanium oxide layer during anodic oxidation is hardly explained.

All the cited references disclosing anodic oxidation teach only the oxidation of titanium, not the incorporation of magnesium. For example, Hall et al. discloses only suitable electrolyte for achieving the desired porous layers such as inorganic acids (for example sulfuric acid, phosphorous acid, and chromic acid) and/or diluted organic acid (for example, acetic acid and citric acid). As consequences, the composition of the oxide layer surface oxide of Hall et al. never contains Mg cations incorporated into the titanium oxide. The teaching of Hall et al. teaches away from the claimed invention.

The examiner merely argued, without factual supporting or technical reasoning, that Vizethum et al. teach an implant a formation of oxide layer, and Kamiya et al. teach magnesium titanate oxide film formed by sintering, and concludes that the combination of two references produces the claimed invention.

Withdrawal of the rejection is respectfully requested.

**Fourth**, the prior art does not suggest or teach the desirability of forming the magnesium titanate oxide film.

To establish a prima facie case of obviousness, three basic criteria must be met. One of the requirements is that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or

to combine reference teachings.

Here, Vizethum teaches that "The oxide coating consists of the same metal and/or the same metal craving as the dental implant, whose surface was transferred by oxidizing into the oxide coating according to invention." (See paragraph [0008]. For the examiner's information, the English of available translation Vizethum al. is at et <a href="http://v3.espacenet.com/textdes?DB=EPODOC&IDX=EP0676179&F=0&QPN=EP0676179">http://v3.espacenet.com/textdes?DB=EPODOC&IDX=EP0676179&F=0&QPN=EP0676179>.)</a> That is, Vizethum et al. teaches the metal of the implant body is the same as the metal of the oxide layer on the surface of the implant body. That is, there is no desirability of modifying the Vizethum et al's teaching. The examiner merely argued that Vizethum's oxide layer may be modified to be magnesium titanate oxide.

Therefore, the examiner failed to establish a prima facie case of obviousness.

Fifth, even if we follow the examiner's reasoning, the ordinary skilled person in the art would change the anodic oxidation of Vizethum into the sintering method.

Even if the examiner would show that there is some suggestion or motivation to modify the titanium oxide layer taught in Vizethum et al. into the magnesium titanate oxide layer Where it is not known that the magnesium titanate oxide film produced by anodic oxidation in a solution containing magnesium results in a novel structure, the ordinary skilled person in the art would follow the sintering method of Kamiya et al. rather than the anodic oxidation method of Vizethum et al. That is, there is no desirability of modifying the sintering method for producing the magnesium titanate film into the anodic oxidation method which is not disclosed in the prior art references.

**Sixth**, in addition, evidence that the implant has unexpectedly a porous layer and a barrier layer in an oxide layer is sufficient to overcome the obviousness rejection.

MPEP §716.02(c) states that:

Evidence of unexpected results must be weighed against evidence supporting *prima facie* obviousness in making a final determination of the obviousness of the claimed invention. *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (Claims directed to a method of effecting analgesia without producing physical dependence by administering the levo isomer of a compound having a certain chemical structure were rejected as obvious over the prior art. Evidence that the compound was unexpectedly nonaddictive was sufficient to overcome the obviousness rejection. Although the compound also had the expected result of potent analgesia, there was evidence of record showing that the goal of research in this area was to produce an analgesic compound which was nonaddictive, enhancing the evidentiary value of the showing of nonaddictiveness as an indicia of nonobviousness.).

Here, the magnesium titanate oxide film produced by the anodizing oxidation in a solution containing magnesium produces unexpected results which are shown in the specification. For example, as stated above, the magnesium titanate oxide film comprises an upper porous layer and a lower barrier layer as shown in FIGS. 1 and 2. Also, the claimed invention has osseoinductive properties and excellent mechanical strength on surfaces of titanium and titanium alloy implants, so as to induce rapid and strong bone binding, thereby leading to successful osseointegration; and a method for preparing the same. The data are specifically described from page 9 to page 13, and FIGS. 1-10.

Therefore, even if the examiner would establish a prima facie case of obviousness by overcoming the above applicant's counterarguments, the evidence of the unexpected results shown in the specification is sufficient to overcome the examiner's obviousness rejection.

Please note that "[I]n order to provide a complete application file history and to enhance the clarity of the prosecution history record, an examiner must provide clear explanations of all actions taken by the examiner during prosecution of an application" and "[w]here the applicant

PATENT P57712

traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the

applicant's argument and answer the substance of it." (See MPEP 707.07(f).) Therefore, if the

examiner does not agree with the applicant's argument, the examiner's answers to all the above

arguments are respectfully requested.

In view of the above, it is submitted that the claims of this application are in condition for

allowance, and early issuance thereof is solicited. Should any questions remain unresolved, the

Examiner is requested to telephone Applicant's undersigned attorney.

A fee of \$230.00 for SMALL ENTITY is incurred by filing a Petition for Two-month

Extension of Time. Applicants' check drawn to the order of Commissioner accompanies this

Amendment. Should the check become lost, be deficient in payment, or should other fees be

incurred, the Commissioner is authorized to charge Deposit Account No. 02-4943 of Applicants'

undersigned attorney in the amount of such fees.

Respectfully submitted,

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15